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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/880,576	06/13/2001	Clifton A. Alferness	59013-331623	7153

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FAEGRE & BENSON LLP
PATENT DOCKETING
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EXAMINER	
SZMAL, BRIAN SCOTT	
ART UNIT	PAPER NUMBER
3736	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/10/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/880,576	ALFERNESS ET AL.	
	Examiner	Art Unit	
	Brian Szmal	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *27 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *18,32-37 and 39-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18,32-37 and 39-41* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *13 June 2001 and 27 February 2007* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 18, 32-37 and 39-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 18 was amended to add "passively" before constrain and the word "passively" is not explicitly set forth in the original disclosure. The disclosure as a whole discusses constraining the heart in a way that does not prevent restricted contraction of the heart (page 11, lines 27-30) and further teaches that the jacket is made of an Atlas knit that is well known to be a knit or fabric that is at least slightly expandable and can stretch in response to a force. However the disclosure as a whole is not clear as to support passively constraining the circumferential expansion of the heart.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 18, 32-37 and 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lederman et al (6,224,540 B1) in view of Gordon et al (5,336,253).

Lederman et al disclose a passive girdle for constraining heart expansion and further disclose accessing the heart (the heart has to be accessed in order to place jacket 30 on the heart); selecting a device (30) sized to be placed on the diseased heart; placing the device (30) on the heart, the device (30) comprising compliant biocompatible material (33) configured to engage a surface of the heart to passively constrain circumferential expansion of the heart (See Column 5, lines 35-36); securing the device (30) on the heart (See Column 5, lines 52-55); the device (30) is secured to the heart using sutures (See Column 5, lines 52-55, attaching the device at 4-6 points along the A-V groove suggests the use of sutures because an adhesive would be incompatible on a beating heart); adjusting the device (30) to snugly conform to the external geometry of the heart (See Column 5, lines 55-57); the biocompatible material (33) is a substantially non-elastic material (See Column 5, lines 26-31, the plastic rings allow expansion of the heart to a specified size and then constrains the heart); and the device (30) is configured to engage a surface of the heart to constrain circumferential expansion of the heart beyond a predetermined maximum volume (See Column 5, lines 26-31, see explanation above).

Lederman et al however fail to disclose passing an electrical current to the heart with the current selected to apply and electrical therapy to the heart; passing the electrical current to the heart is accomplished using electrical elements; the electrical

elements are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy.

Gordon et al disclose a pacing and defibrillation lead for providing therapy to a heart and further disclose passing an electrical current to the heart with the current selected to apply and electrical therapy to the heart; passing the electrical current to the heart is accomplished using electrical elements (10); the electrical elements (10) are pacer leads; the electrical therapy is a defibrillating therapy; and the electrical therapy is a pacing therapy. See Column 2, lines 40-48; Column 3, lines 61-68; and Column 6, lines 34-54.

Since both Lederman et al and Gordon et al both apply a therapy to a diseased heart, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Lederman et al to include the application of electrical therapy to the heart, as per the teachings of Gordon et al, since it is well known in the art to utilize pacing and/or defibrillation to treat an abnormally-beating heart.

Response to Arguments

5. Applicant's arguments filed February 27, 2007 have been fully considered but they are not persuasive. The Applicants have argued that Gordon et al cannot be combined with Lederman et al, since Gordon et al fail to disclose any teaching of treating congestive heart failure. Gordon et al disclose a means of defibrillating a heart in order to achieve the correct heart rhythm, which is necessary when the heart is in a

diseased state. In the current specification, the current invention is nothing more than a heart jacket (for treating congestive heart failure) that has the ability to allow passage of electrical elements and electrical current through the jacket (for defibrillating the heart). See page 13, lines 17-24. Lederman et al teach the use of a heart jacket that constrains the heart with an open cell construction, just as taught by the current invention. Since Lederman et al provide an open cell construction, it would inherently allow the passage of an electrical current or even electrical leads through the jacket. Therefore, one of ordinary skill in the art would be able to combine the Lederman et al with Gordon et al to obtain the current invention.

In response to applicant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, both Lederman et al and Gordon et al provide means for treating the heart. Lederman et al provide a heart jacket that treats cardiomyopathy, which is the enlarging of the heart or ventricular dilatation. Gordon et al provides a means of treating the heart through the use of defibrillation. It is well known to one of ordinary skill in the art that defibrillation has been used when the heart is unable to maintain a normal rhythm, especially when a heart is diseased or is enlarged due to cardiomyopathy.

Conclusion

6. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Szmal whose telephone number is (571) 272-4733. The examiner can normally be reached on Monday-Friday, with second Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BS

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